REMARKS

Applicant respectfully requests reconsideration. Claims 1-5, 8-15, 19-23, 28-33, 44, 46-58, 64-66, 71-74, 77-81, 84, 85, 89, 95, 96, 98 and 100-105 are pending in this application. Claims 5, 13, 15, 46-58, 64-66, 71-74, 77, 81, 84, 85, 89, 90, 95, 96 and 98 have been withdrawn from consideration. No claims have been amended. No new matter is added.

Drawings

Applicant acknowledges that the Examiner has accepted the drawings filed on April 27, 2004.

Request for Continued Examination

Applicant acknowledges that the Examiner has accepted the Request for Continued Examination, filed July 24, 2006 and has entered the Amendment filed March 23, 2006.

Double Patenting Rejection

Claims 1-3, 8-10, 17, 18, 20, 21, 23, 30-33 and 100-105 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 41-46, 52-56 and 58 of copending Application No. 10/816,220.

US Serial No. 10/816,220 is assigned to Coley Pharmaceutical Group, Ltd. and names Heather Davis and Michael McCluskie as inventors. The instant Patent application is assigned to Coley Pharmaceutical Group Inc. and names Arthur Krieg as an inventor. The two patent applications have different inventors and different assignees. It is unclear what is the basis for a double patenting rejection.

Rejection Under 35 U.S.C. § 112

Claims 1, 3, 4, 8-12, 14, 19-21, 23, 28-33, 44, 100-102, 104 and 105 are rejected under 25 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

The Examiner alleges that the recitation of "comprising" in Claim 1 indicates that there are other structural components to the claimed oligonucleotide. The term comprising is open language

which allows the inclusion of other elements beyond the specified elements. However, in claim 1 and the claims dependent thereon specific limits are placed on the oligonucleotide. The oligonucleotide must include a core structure of 24 nucleotides in length. Applicants have asserted that it is this core structure that confers immunostimulatory activity on the claimed molecules. Many claims recite the term "comprising" followed by a core structure. It is only required that the minimal elements be recited. A claim directed to an oligonucleotide is no different.

The Examiner alleges that the claims do not set any function or specific structure for the claimed oligonucleotides. Contrary to Examiner's assertions, the claimed invention is not described solely in terms of methods of its making coupled with its function. There is art-recognized correlation between the structure of the invention and its function. As discussed in the specification, is has been understood and held in the art that immune stimulatory effects of bacterial DNA are a result of the presence of unmethylated CpG dinucleotides in particular base contexts (CpG motifs), which are common in bacterial DNA, but methylated and underrepresented in vertebrate DNA (background of the invention) (Krieg *et al.*, 1995 Nature 374:546-549; Krieg, 1999 Biochim. Biophys. Acta 93321:1-10). The immune stimulatory effects of bacterial DNA can be mimicked with synthetic oligodeoxynucleotides containing these CpG motifs. These immune stimulatory effects of native phosphodiester backbone CpG ODN are highly CpG specific in that the effects are dramatically reduced if the CpG motif is methylated, changed to a GpC, or otherwise eliminated or altered (Krieg *et al.*, 1995 Nature 374:546-549; Hartmann *et al.*, 1999 Proc. Natl. Acad. Sci USA 96:9305-10). In early studies, it was thought that the immune stimulatory CpG motif followed the formula purine-purine-CpG-pyrimidine-pyrimidine (Krieg *et al.*, 1995 Nature 374:546-549; Pisetsky, 1996 J. Immunol. 156:421-423; Hacker *et al.*, 1998 EMBO J. 17:6230-6240; Lipford *et al.*, 1998 Trends in Microbiol. 6:496-500). It has now been discovered that oligonucleotides having a core 24 nucleotide motif have strong immunostimulatory capability. The instant invention claims the novel structures of such oligonucleotides (ODNs) and their function in stimulating various types of immunogenic responses as illustrated by the examples and drawings of the instant specification.

The biomolecule sequences of the invention are not described merely by functional characteristics. The biomolecule sequences of the invention are described by structure, formula, name, and physical properties – as oligonucleotides with specific sequences, specific lengths, and

specific internucleotide linkages. In addition, modifications to the bases, nucleosides, and the linkages as envisaged by the instant invention are also described. The specific sequence requirements, linkages and structures of the oligonucleotides of the instant invention are shown the summary of the invention and the detailed description. The specification describes the structures and function of the novel ODNs that comprise the invention.

A skilled artisan can immediately envision the product claimed from the disclosure. A skilled artisan could easily select an appropriate oligonucleotide based on the disclosure that includes the core 24 nucleotide motif and that would stimulate the desired immunogenic response. Furthermore, a skilled artisan could easily synthesize and use such a compound because the art of nucleic acid synthesis, formulation and administration is well developed and such a process would not be beyond what is routinely carried out in the art. The specification teaches one of ordinary skill in the art *de novo* synthesis of nucleic acids using any number of procedures (see page 21, lines 23-24). The specification also provides detailed instructions to one of ordinary skill in the art for introducing modifications into an oligonucleotide (see pages 14-21).

The claims are adequately described. The specification describes the properties of the claimed oligonucleotides so as to reasonably convey to the skilled artisan the invention; namely, oligonucleotides having a core motif of 24 nucleotides in length that confers immunostimulatory capacity on the oligonucleotide. Further characteristics such as sequence, length and internucleotide linkages are described in detail in the specification as well. Examples of the specific immunostimulatory activity of the core oligonucleotide are included in the Examples and Drawing sections. The specification teaches one of ordinary skill in the art how to use the nucleic acids both *in vitro* and *in vivo*. For *in vivo* use, the specification further teaches how to formulate, dose and administer the nucleic acids, and to whom to administer the nucleic acids. Therefore, Applicants have clearly demonstrated that at the time of the invention they were in possession of the claimed genus by presenting examples and a specification that shows that the invention was "ready for patenting".

Additionally claims 2 and 103 recite a nucleic acid that consists of the nucleotide sequence of SEQ ID NO: 1. No basis has been provided for rejecting this claim which is composed of only a 24 nucleotide sequence.

Applicants respectfully request that the Examiner withdraws the rejection under first paragraph, 35 U.S.C. §112.

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Dated: March 21, 2007

Respectfully submitted,

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